JUL 19 2006

TROKAMED

K 060233

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

DATE OF APPLICATION: 2006-01-26

Submitted by: Trokamed GmbH
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1. DEVICE DESCRIPTION

Trade Name: Edoscopes and accessories

Common Name: Endoscopes

The Trokamed GmbH Endoscopes and accessories consist of:

- Various manually operated surgical instruments
- Several Trocar sleeves and accessories, Verres insufflation cannula and suction-/irrigation systems
- Several Endoscopes (Arthroscope, Cystoscope)

2. CLASSIFICATION

Device:	Endoscope and accessories
Panel:	876
Product Code:	GCJ
Device Class:	2
Regulation Number:	876.1500

3. INTENDED USE

The laparoscopes and accessories are intended for use in providing access to and visualization of body cavities, organs, and canals to perform various diagnostic and therapeutic surgical procedures.
The arthroscope is indicated for illumination during joint examinations, arthroscopies, biopsies and diagnosis of joint disease in minimally invasive procedures of the knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle and elbow.
The cystoscopes and accessories are used for visualizing body cavities and organs (via natural passages). For examination, diagnosis and for therapy in conjunction with endoscopic accessories / auxiliary instruments through the schope´s working channel.
The instruments are reusable; they are intended to be cleaned, sterilized and reused.

4. SUBSTANTIAL EQUIVALENCE

Manufacturer	510(k) Number	Device name
A Richard Wolf	K 991718	Operating Laparoscope, 10-5mm, angeled...
B Hans Hermann	K 051610	Laparoscopes and accessories
C Ackermann	K 974382	Ackermann surgical instruments

5. BIOCOMPATIBILITY

The biocompatibility has been approved based on ISO 10993 parts one, five and ten by the accredited Laboratory Bioservice.

6. STERILIZATION BY USER

Trokamed GmbH delivers all endoscopes and accessories in Non-Sterile conditions. The user may sterilize these devices by using a validated and applicable sterilization process.
Trokamed GmbH recommends to use a steam-sterilizer that uses a validated sterilization cycle of 134°C / 270°F, 3 bar, for 10 minutes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trokamed GmbH
% Karhlheinz Trondle
President
Kleine Breite 17
Geisingen, Germany 78187

JUL 19 2006

Re: K060233
Trade/Device Name: Endoscopes and accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 21, 2006
Received: June 28, 2006

Dear Karhlheinz Trondle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060233

Indications for Use

510(k) Number (if known): K060233

Device Name: Endoscopes and accessories

Indications For Use:

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The cystoscopes and accessories are used for visualizing body cavities and organs (via natural passages). For examination, diagnosis and for therapy in conjunction with endoscopic accessories / auxiliary instruments through the scope's working channel.

The instruments are reusable; they are intended to be cleaned, sterilized and reused.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucholz for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060233